

**REMARKS**

It is noted that the examiner has not initialed several outstanding PTO/SB/08A forms. It is respectfully submitted that such initialed forms be mailed to applicant. Further to the “letter” submitted on August 4, 2009, it is noted that new Office Actions have been issued in the related applications serial numbers 11/763,125, 11/763,116 and 10/472,844. It is again understood that the PTO prefers that these Office Actions not be scanned into the file for this particular application since they are readily available to the examiner. However, should the examiner desire to have these documents scanned, the undersigned would be happy to comply.

It is also noted that the Bates reference on which the examiner relies is part of a family which also includes 11/141,574, 12/359,884 and 11/234,702.

The examiner alleges on page 2 that the term “during stent implantation” in claim 49 is not defined by the claim and also alleges that the term “a short time” in prior claim 50 is interpretable to be any length of time from an instant to even hours. These allegations are not correct because they ignore the context of the individual claims which provides a very definite functional time frame. Nevertheless, a time of duration for the contact involved has been inserted in claim 49 based on page 11, lines 23 – 26 of the specification, thereby rendering this issue moot.

The examiner continues to allege that the Dror reference can be combined with Bates to suggest claimed subject matter, such as that of independent claims 1 and 24. However, the combination of these references does not suggest this subject matter.

There is no disagreement that the Bates disclosure teaches that when surfaces are roughened, then drugs such as lipophilic drugs such as paclitaxel can be coated thereon without co-ingredients intended to slow down their release such as containment materials, layers, matrices, etc. That roughness is required for this result is clear in Bates, e.g., from page 3, col. 1, lines 41-57, paragraphs 16, 17, 18 (especially the second sentence), 20, 85 and many other locations. Note also paragraph 84 which compares a roughened (grit abraded) surface with a “control” surface (not roughened, only plasma treated) to demonstrate that the

non-control, i.e., the roughened surface, is “successful” while the control, non-roughened surface is not.

Thus, Bates clearly teaches that one can administer drugs such as paclitaxel without the containment materials and the like, but only when the coated surface is roughened as defined in Bates. In no way does the Dror reference affect this clear Bates disclosure.

The Dror disclosure (filed about 11 ½ years prior to the filing of the Bates disclosure) does deal with the coating of balloons with drug materials. However, it does not relate to the problem of when one can effectively administer lipophilic drugs such as paclitaxel in the absence of containment materials (such as layers or coatings as explained in Bates (paragraphs 11, 19, etc)) in order to achieve immediate release. Thus, the various teachings referred to by the examiner in Dror are in essence irrelevant to the clear deficiency of Bates et al. with respect to the subject matter claimed in this application. This, of course, is not unexpected in view of the fact that Bates is discussing a much later generation of balloon coating technology. With respect to claims such as 6 and 24, Dror is even further removed since it contains no mention of balloon areas covered by folds being coated with a drug that was dried after application.

Consequently, as can be seen, the combination of Bates and Dror, which underlies all of the examiner’s rejections, does not suggest the claimed features as alleged by the examiner. Consequently, for this reason alone, all rejections are unsound. In view of this principal deficiency in all the rejections, the examiner’s comments with respect to the other secondary references are moot. No agreement with any of these statements is to be implied. Similarly, other statements made by the examiner with respect to Bates and Dror not discussed herein specifically, are not particularly germane to this roughness requirement. No agreement with any of these statements is to be implied.

In paragraph 9, as well as in paragraph 20, the examiner makes an argument alleged to explain why the Bates disclosure in its paragraph 68, involving the presence of specified ranges of paclitaxel on an essentially permanently placed stent, would teach a skilled worker the amount suitable for a balloon to be placed in contact with the same tissue for only short times on the order of minutes. This argument is:

Bates discloses that when using paclitaxel, the drug need only contact the target area for a very short time to provide lasting effects (page 11, paragraph 0100). Given this teaching, one of skill in the art would recognize that a balloon which contacts the treatment site for a short time can be as effective as a stent which remains at the site for a longer time period so the concentration used for both the balloon and the stent would be similar.

It is respectfully submitted that this argument is not logical. Bates gives no explanation of how much of the drug loaded on the stent is released over any particular time periods. He also gives no hint of which amount should be loaded over the much shorter time periods at issue in order to achieve similar effects. Nothing implies that the long term loading amounts and the short time loading amounts should be "similar." For instance, Bates does not state how much of the drug loaded on the stent designed for such permanent-type contact is released in the shorter time periods which would be involved with balloon catheters. Without this information there is no support for the conclusion reached by the examiner. Consequently, the disclosure in paragraph 100 of Bates that keeping paclitaxel "around" for periods of time like 20 minutes enables it to have "prolonged effects for up to, for example, fourteen days," is not sufficient to enable a skilled worker to expect stent loadings designed for contact periods of many months or years would also be applicable for time periods such as twenty minutes. Thus, for this reason also, the claimed subject matter is not obvious in view of Bates combined with Dror. In any event, this point is moot for the reasons discussed above with respect to the Bates requirement for roughening.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/Anthony J. Zelano/  
Anthony J. Zelano, Reg. No. 27,969  
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO  
& BRANIGAN, P.C.  
2200 Clarendon Boulevard, Suite 1400  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410  
AJZ:klb

Date: December 7, 2009